REMARKS

Claims 24, 27 and 28 are now pending in the present application. Claims 24, 27 and 28 have been amended. Claims 14-23 have been formally canceled at the Examiner's request. Additionally, claims 25-26 and 29-30 have been canceled. Finally, the title has been amended as previously suggested by Applicant.

Applicant has carefully studied the outstanding Office Action. The present Response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of this application are respectfully requested. No new matter has been added by any of the amendments to the specification. Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

CLAIM REJECTIONS – 35 U.S.C. §112

Claims 25, 26 and 28-30 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, as well as 35 U.S.C. §112, second paragraph, for being indefinite. The Examiner's arguments have been carefully considered by the Applicant and claims 25-26 and 29-30 have been canceled. Claim 27 has been amended to correct a typographical error. Claim 28 has been amended to specify that the gel composition in question should be topically administered to the skin of an animal in need thereof. Further, Examiner states he "could find nowhere within the instant disclosure (including the original claims) which supports a gel composition which comprises or consist of 4-nerolidylcatechol (per se)." As previously stated, although it is not specifically mentioned in the specification, one skilled in the art would know that 4-nerolidylcatechol could be obtained by any other means (other plant extract, organic synthesis, etc). The fact that the exact words in question may not be in the specification is not important. *In re Wright,* 866 F.2d 422, 425, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). In determining whether the written description requirement is satisfied, the specification as a whole must be considered. *In re Wright*, 866 F.2d 422, 425, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). Figure 3 corresponds to the 4-nerolidylcatechol concentration in the skin of mice. The requisite description may be made through drawings or formulas. *In re Wolfensperger*, 302 F.2d 950, 955, 133 U.S.P.Q. 537, 541 (C.C.P.A. 1962); *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). Further, example 1 discloses that an

appropriate dosage "will be effective with the presence of at least 0.1% of 4-nerolidylcatechol."

Examiner also rejects claim 24 under 35 U.S.C. §112, second paragraph, but fails to support his rejection of claim 24. In rejecting a claim under the second paragraph of 35 U.S.C. § 112, it is incumbent upon the Examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and clarity the particular area set out and circumscribed by the claims. *Ex Parte Wu*, 10 USPQ2d 2031, 2033 (B.P.A.I. 1989); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (C.C.P.A. 1970). Thus, the Examiner has the burden of providing reasons why the terminology is indefinite or would not readily be understood by those of ordinary skill in the art. Examiner is respectfully invited to either withdraw the rejection as to claim 24 or provide reasons why the terminology is indefinite.

CLAIM REJECTIONS – 35 U.S.C. §103

Claims 24-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 20000) in view of Wheeler (US 6,165,479).

Claims 24-30 are further rejected under 35 U.S.C. § 103(a) as being unpatentable over Uchiyama et al. (JP 2001122763) in view of Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479). In addition, Examiner cites the admitted state of the art, if necessary.

Claims 24 and 28 have been amended. In *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), the Federal Circuit expressly rejected the notion "that ranges found in the applicant's claim language must correspond exactly to ranges disclosed in the parent." This is because neither the Patent Act nor the case law requires such detailed disclosure. See *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533 (Fed. Cir. 1992) ("[The applicant] does not have to describe exactly the subject matter claimed."); *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1566 (Fed. Cir. 1991). Rather, the Patent Act and this court's case law require only sufficient description to show one of skill in the refining art that the inventor possessed the claimed invention at the time of filing. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1001 (Fed. Cir. 2000). To satisfy the written description requirement, the claimed invention

need not be expressed ipsis verbis in the original specification. *In re Wertheim*, 541 F.2d 257, 262, 190 U.S.P.Q. 90, 96 (C.C.P.A. 1976). In *In re Wertheim*, the CCPA found that a claimed range of 35% to 60% based upon a written description disclosing a range of 25% to 60% did meet the description requirement. *See also* MPEP 2163.05 III.

Examiner is correct in his assertion that none of the cited references "expressly teach providing the skin therapeutic Pothomorphe umbellata extract within a skin gel composition - including one containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed." However, Applicant maintains that the second Ropke reference does not teach a gel composition, but rather an oil/water emulsion, which Examiner misconstrues to "reasonably reads upon a 'gel composition' as instantly claimed." Emulsions are unstable and thus do not form spontaneously; instead, to form an emulsion, constant energy input through shaking, stirring, homogenizers, or spray processes is needed. On the other hand, while gels are mostly liquid in composition, exhibiting densities similar to liquids, they have the structural coherence of a solid without constant energy input.

Moreover, although Wheeler does teach that carboxymethylcellulose, propylene glycol, methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, the specific gel composition as instantly claimed would not have been obvious in view of the state of the art. In fact, determining the appropriate amount range and the specific ingredients that would provide for the appropriate skin penetration of 4-nerolidylcatechol was not a matter of routine optimization. A prior art suggestion for virtually endless experimentation cannot form a proper prima facie case of obviousness.

It is well known that percutaneous penetration, that is, the passage through the skin, involves the dissolution of a drug in a vehicle, diffusion of the solubilized drug from the vehicle to the surface of the skin, and the penetration of the drug through the layers of the skin, mainly the stratum corneum. This penetration may be improved by selecting the appropriate vehicle. Many factors may influence the extent of percutaneous absorption of a drug. Partitioning of the drug of interest between the vehicle and the stratum corneum results in a concentration gradient developing across the skin, which is influenced by drug-vehicle-skin interactions. Thus, there is no doubt that the release of a drug from a topical pharmaceutical preparation can be effectively influenced by the vehicle in which it is applied. An appropriate formulation of the topical agent will ensure that it exerts its maximal activity on the skin. The primary requirement for topical

therapy is that a drug incorporated into a vehicle reaches the skin surface at an adequate rate and in sufficient amounts. The flux is actually proportional to the gradient of thermodynamic activity, rather than to the concentration of the drug. This activity changes according to different formulations and the release of a substance from the vehicle will be favored by selecting vehicles with low affinity for the penetrating molecule. By employing unusual amounts of propylene glycol in the formulation – 10% (usually incorporated 1-5%), Applicants were able to dissolve and stabilize the 4-Nerodiycathecol, a highly lipophilic molecule, in an totally hydrophilic gel formulation, while at the same time delivering the active principle into the skin at an adequate rate and in sufficient amounts, as shown in Figure 3. In Figure 3, Applicant makes a correlation between the percentage of 4-Nerolidylcathecol present in the skin and the efficacy results shown in Figure 5 demonstrating the importance of an appropriate gel composition for an adequate penetration of the drug.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 706.02(j). Further, the mere fact that the prior art could be readily modified to arrive at the claimed invention does not render the claimed invention obvious; the prior art must suggest the desirability of such a modification. *In re Ochiai*, 71 F.3d 1565, 1570, 37 U.S.P.Q.2d 1127, 1131 (Fed. Cir. 1996); *In re Gordon*, 733 F.2d 900, 903, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Merely stating that the modification would have been obvious to one of ordinary skill without identifying an incentive or motivation for making the proposed modification is insufficient to establish a prima facie case. Finally, even if the prior art references suggest trying what the claimed invention has done, but carries no reasonable expectation that the result could be successful, the combination cannot be properly made. The present invention in claims 24 and 28 include specific ranges not disclosed by any of the cited prior art, even when their teachings are combined. Therefore, Applicant respectfully requests that Examiner withdraw rejects over claims 24, 27 and 28 as amended.

CONCLUSION

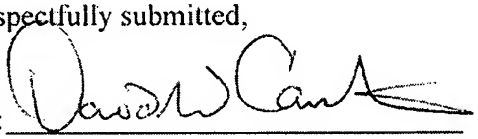
In light of the amendments and the arguments made by Applicants above, as well as the evidence previously submitted, Applicants submit that all existing, examined claims are now in a condition for allowance. Applicants respectfully request that Examiner withdraw all restrictions and rejections with regard to the above-referenced claims in reliance on one or more of the grounds submitted by Applicants.

If there are any outstanding issues that the Examiner feels may be resolved by way of telephone conference, the Examiner is invited to call David Carstens at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

The Commissioner is hereby authorized to charge any payments that may be due or credit any overpayments to CARSTENS & CAHOON, LLP Deposit Account 50-0392.

Respectfully submitted,

Dated: November 3, 2008

By: 

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